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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,755	07/18/2003	Daniel John Smith	1171/39359A	9139

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EXAMINER	
RAGONESE, ANDREA M	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 08/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,755	SMITH ET AL.	
	Examiner	Art Unit	
	Andrea M. Ragonese	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *19-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on February 17, 2005 has been entered. Examiner acknowledges that **claims 1-18** have been amended. Subsequently, **claims 1-18** are under consideration, while **claims 19-59** have been withdrawn from further consideration.

Priority

2. Receipt is acknowledged of the Petition to Accept Unintentionally Delayed Priority Claim Under 37 C.F.R. §1.55(c). This petition, filed on February 17, 2005, has been forwarded to the Office of Petitions for a decision on the merits.

Terminal Disclaimer

3. The terminal disclaimer filed on February 17, 2002 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patent 6,769,431 B2 has been reviewed and is NOT accepted by the Examiner.

4. The terminal disclaimer does not comply with 37 CFR 1.321(b) and/or (c) because the application/patent being disclaimed has been improperly identified since the number used to identify the patent being disclaimed is incorrect. The correct number is ***US 6,769,431 B2*** (not 6,523,538 B1, as currently recited).

As a result, the nonstatutory obviousness-type double patenting rejection, as stated in the previous Office action, has been hereinafter reiterated and still stands.

Response to Arguments

5. Applicant's arguments, see page 15, filed February 15, 2005, with respect to the objection to the specification have been fully considered and are persuasive. The objection to the specification has been withdrawn.

6. Applicant's arguments, see pages 15-17, filed February 15, 2005, with respect to the rejection of **clams 1-18** under 35 U.S.C. §112, first paragraph, have been fully considered and are persuasive. Therefore, rejection under 35 U.S.C. §112, first paragraph, has been withdrawn, and the earlier effective filing date of May 8, 2001 has been granted.

7. Applicant's arguments, see pages 15-17, filed February 15, 2005, with respect to the rejection of **claims 1-3** and **5-7** under 35 U.S.C. §102(a) have been fully considered but are moot in view of the withdrawal of the rejection under 35 U.S.C. §112, first paragraph, and the grant of the earlier effective filing date of May 8, 2001.

8. Applicant's arguments, see pages 17-18, filed February 17, 2005, with respect to the rejection of **claims 1-3** and **5-7** under 35 U.S.C. §102(e) have been fully considered but they are not persuasive.

In response to applicant's arguments, the recitation of an "expiratory limb for a breathing circuit" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535

F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). As currently recited in **claims 1-3** and **5-7**, the prior art of record fully anticipates the structure of the claimed invention and therefore, the 102(e) rejection as stated in the previous Office action is hereinafter reiterated and hereby made **FINAL**.

9. Applicant's arguments, see pages 18-19, filed February 17, 2005, with respect to the rejections of **claims 4, 8-12** and **14-18** under 35 U.S.C. §103(a) have been fully considered but they are not persuasive. See Examiner's response above to arguments for **claims 1-3** and **5-7**. Therefore, the 103(a) rejections as stated in the previous Office action are hereinafter reiterated and hereby made **FINAL**.

10. Applicant's arguments, see pages 18-19, filed February 15, 2005, with respect to the rejection of **claims 8, 9** and **13** under 35 U.S.C. §103(a) have been fully considered and are persuasive. Therefore, the rejection under 35 U.S.C. §103(a) has been withdrawn since the earlier effective filing date of May 8, 2001 has been granted and the prior art of record (US 2003/0070680) is no longer considered a valid prior art reference based in its filing date (October 16, 2001), which is after the filing date (May 8, 2001) of the parent application (09/850,797) of the instant invention.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

12. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

13. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. **Claims 1-18** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of ***U.S. Patent No. 6,769,431 B2 by Smith et al.*** in view of Wikefeldt (US 6,523,538 B1). Smith et al. discloses an breathing circuit limb comprising all the limitations in **claims 1-18**, with the exception of a water vapour flow path from the exhalation flow passage to ambient air through said material. However, the use of this type of flow path in which the water vapour passes through the hydrophilic material from the exhalation flow passage and then exits to ambient air in order to prevent the build up of condensation in the exhalation flow passage was known at the time the invention was made. Specifically, Wikefeldt teaches a water vapor flow path through chamber **142** from an enclosing wall of tube **140**, which serves as the exhalation flow passage in dryer **100*b***. Water vapour

from the breathing gases passes through a moisture permeable element of tube **140** into chamber **142** and then exits from chamber **142** to the ambient environment by way of outlet **146** (column 5, lines 38-60). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the breathing circuit limb of Smith et al. by altering the water vapour to exit from the exhalation flow passage to the ambient air because it is well known in the art, as taught by Wikefeldt, to reduce condensation in the breathing circuit while "[removing] the water vapor from the breathing gases" (column 2, lines 50-54).

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. **Claims 1-3** and **5-7** are rejected under 35 U.S.C. 102(e) as being anticipated by Wikefeldt (US 6,523,538 B1).

Regarding **claims 1** and **5-7**, Wikefeldt teaches an apparatus **100*b*** including: an inlet **106**; an outlet **124**; an enclosing wall defining a substantially singular exhalation flow passage **140** between said inlet **106** and said outlet **124**, at least a region of said enclosing wall being of a material that allows the passage of water vapour without allowing the passage of liquid water or respiratory gases; and a water vapor flow path

from said exhalation flow passage **140** to ambient air though said material. Water vapour from the breathing gases passes through a moisture permeable element of exhalation flow passage **140** into chamber **142** and then exits from chamber **142** to the ambient environment by way of outlet **146** (column 5, lines 38-60).

Regarding **claims 2-3**, the exhalation flow passage material is "formed of the water vapor permeable material made and sold by Perma Pure, Inc. of New Jersey, USA under the trademark 'Nafion'" (column 5, lines 42-45), which is a perfluorinated polymer membrane material.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wikefeldt (US 6,523,538 B1), as applied to **claim 1** above, in view of Skarstrom et al. (US 3,735,558). Wikefeldt discloses an apparatus comprising all the limitations recited in **claim 4**, with the exception of the material being a hydrophilic polyester block copolymer. However, the use of this type of water vapor permeable material was known at the time the invention was made. Specifically, Skarstrom et al. teaches the use of a hydrophilic polyester block copolymer for drying air by separating out the water vapor from the air by allowing the water vapor to permeate through the material (column 12, lines 46-58), leaving behind the dried air. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the exhalation flow passage **140** of Wikefeldt by modifying it to be constructed of a hydrophilic polyester block copolymer (instead of a perfluorinated polymer) because it is well known in the art, as taught by Skarstrom et al., to use this type of permeable material in order to separate the water vapor from the air in order to dry the air and reduce condensation in the apparatus.

21. **Claims 8-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wikefeldt (US 6,523,538 B1), as applied to **claims 1** and **5** above, in view of Coleman et al. (US 5,233,996). Wikefeldt discloses an apparatus comprising all the limitations recited in **claims 8-9**, with the exception of disclosing the type of manufacturing method used to make the exhalation flow passage. However, the use of extrusion to produce the exhalation flow passage conduit was known at the time the invention was made. Specifically, Coleman et al. teaches the use of extrusion for producing a NAFION® conduit. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to produce the exhalation flow passage conduit of Wikefeldt by the method of extrusion because it is well known in the art, as taught by Coleman et al., to use the manufacturing method of extrusion in order to produce a water permeable conduit (column 9, line 36 through column 10, line 28).

22. **Claims 8-9** and **13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wikefeldt (US 6,523,538 B1), as applied to **claims 1** and **5** above. Wikefeldt discloses an apparatus comprising all the limitations recited in **claims 8-9** and **13**, with the exception of disclosing the type of manufacturing method used to make the exhalation flow passage tubing. MPEP §2113 states "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Consequently, the process recitation of the tube

being formed by blown-film extrusion is noted but not structurally distinguishing. In addition, the use of blown-film extrusion to produce the tube was known at the time the invention was made. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to produce the exhalation flow passage conduit of Wikefeldt by the method of blown-film extrusion because it is known in the art to use this type of method to produce tubing.

23. **Claims 8-12** and **14-18** rejected under 35 U.S.C. 103(a) as being unpatentable over Wikefeldt (US 6,523,538 B1), as applied to **claims 1** and **5** above, in view of Carlson et al. (US 4,337,800). Wikefeldt discloses an apparatus comprising all the limitations recited in **claims 8-12** and **14-18**, with the exception of longitudinal strips running the complete length of the exhalation flow passage conduit, produced by the manufacturing method of extrusion, as well as helically wound strips on the conduit. However, the use of an extruded conduit with longitudinal strips and/or helically wound strips was known at the time the invention was made.

Specifically, regarding **claims 8-10** and **12**, Carlson et al. teaches the use of an extruded hose (column 2, lines 7-9) that contains longitudinal strips **10** running the complete length of the conduit, as shown in Figure 1.

Regarding **claim 11**, Carlson et al. also teaches helically wound strips, also shown in Figure 1, that extend parallel to the axis of the conduit and are bonded together (column 2, lines 7-15).

Further, regarding **claim 14**, Carlson et al. discloses lateral reinforcement to provide for a crush resistant hose (column 2, lines 43-45).

Regarding **claims 15-17**, the lateral reinforcements include annular corrugations or helical beads **30** distributed over the length of the conduit.

Regarding **claim 18**, the hose has ribs, which are skeletal reinforcing structures. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the exhalation flow passage conduit of Wikefeldt by adding at least one longitudinal strip and/or a helically wound strip because it is well known in the art, as taught by Carlson et al., to add these types of structures to a conduit in order to add structural reinforcements to produce, by the method of extrusion, an inexpensive and stronger, crush-resistant and flexible hose, which would be less likely to be damaged with repeated use (column 1, lines 54-57).

Conclusion

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese whose telephone number is 571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR
July 11, 2005

Henry Bennett
Supervisory Patent Examiner
Group 3700